

### REMARKS

Claims 1-8, 10, 13, and 17-21 are canceled herein. Support for the amendments of claim 9 can be found throughout the specification, specifically on page 3, line 21-23, and on page 6, line 12-15. Claims 14-16 are amended to provide the full name for the abbreviation HGF, as supported throughout the specification, specifically on page 1, line 7-8. Support for the additional amendments of claim 14 can be found in the specification on page 5, line 29 to page 6, line 9.

The priority claim is amended remove the statement regarding incorporation by reference. The present application is a translation of the text of the PCT application.

No new matter is added. Reconsideration of the subject application is respectfully requested.

### Telephone Conference

Applicants thank Examiner Whiteman for the helpful telephone conference of February 20, 2003.

### Restriction Requirement

Claims 3, 11 and 18 are canceled herein in response to the restriction requirement, and not for reasons pertaining to patentability.

### Priority Claim

Applicants thank Examiner Whiteman for acknowledging the priority claim. Applicants further thank Examiner Whiteman for the helpful telephone conference of February 20, 2003. As discussed with Examiner Whiteman, PCT Application No. PCT/JP00/07502, filed October 26, 2000, and Japanese Patent Application No. 11/309984, filed October 29, 1999, were published in Japanese. The subject application is an English translation of PCT Application No. PCT/JP00/07502. As such, the priority claim has been amended to remove the statement regarding incorporation by reference, as discussed in the telephone conference.

### **Objection to Claims 1 and 9**

Claims 1 and 9 were objected to for having a grammatical error in the preamble. Claim 1 has been canceled, rendering the rejection moot as applied to this claim. The preamble of claim 9 has been amended as suggested in the Office action, thereby removing the objection.

### **Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1-21 were rejected as allegedly not being enabled by the specification. Claims 1-8, 10, 13, and 17-21 have been canceled, rendering the rejection moot as applied to these claims. Applicants respectfully disagree with the rejection as applied to claims 9, 11, and 14-16 as amended.

Claim 9 has been amended to recite that a therapeutically effective amount of HGF is administered to the muscle of an ischemic site. The Office action notes that the specification is enabling for (1) a therapeutic agent for reducing diabetic ischemic disease in a subject, the agent comprising a therapeutically effective amount of hepatocyte growth factor (HGF) and (2) a method of reducing diabetic ischemic disease in a subject comprising administering to an ischemic site a therapeutically effective amount of HGF (see page 5 of the Office action). As the specification clearly is enabling for a method of reducing diabetic ischemic disease in a subject comprising administering a therapeutically effective amount of HGF to an ischemic site. Applicants submit that amended claim 9, and dependent claims thereof, are fully enabled.

Reconsideration and withdrawal of the rejection are respectfully requested.

### **Rejections Under 35 U.S.C. § 112, second paragraph**

Claim 16 was rejected as there is insufficient antecedent basis for "the subject." Claim 16 depends from claim 9. Claim 9 has been amended to recite "a subject." Applicants submit that the amendment of claim 9 provides proper antecedent basis for the term "the subject" in claim 16. Thus, the amendment of claim 9 removes the rejection.

Claims 17-21 are rejected as allegedly not including sufficient steps in the method. Applicants respectfully disagree with this assertion. However, claims 17-21 have been canceled, rendering the rejection moot.

### **Rejections Under 35 U.S.C. § 101**

Claims 17-21 were rejected as allegedly not being directed to a process that can be claimed. Claims 17-21 have been canceled, rendering the rejection moot.

### **Obviousness-Type Double Patenting**

Claims 1-7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 and 26-28 of co-pending U.S. Patent Application No. 09/857,719. Applicants respectfully disagree with this assertion. However, claims 1-7 have been canceled, rendering the rejection moot.

Claims 1-7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of co-pending U.S. Patent Application No. 09/986,374. Applicants respectfully disagree with this assertion. U.S. Application No. 09/986,374 is directed to a method of preparing low allergic rubber latex. For the Examiner's convenience, a copy of the first page of this published application, and a copy of the issued claims, is attached. However, in the interest of advancing prosecution, and clearly not for reasons pertaining to patentability, claims 1-7 have been canceled, rendering the rejection moot.

### **Rejections Under 35 U.S.C. § 102**

Claims 1-7 and 17-20 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,248,722. Applicants respectfully disagree with this assertion. However, claims 1-7 and 17-20 have been canceled, rendering the rejection moot.

Claims 1-5, 7, 9-10, and 17-19 (as product claims) were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,562,225. Claims 1-5, 7, 10 and 17-29 have been canceled, rendering the rejection moot as applied to these claims. U.S. Patent No. 5,562,225 teaches a DNA encoding HGF. Claim 9 was rejected over U.S. Patent No. 5,562,225 "as a product" (see the Office action at page 14). Claim 9 has been amended to clarify that a process is claimed. Claim 9 has also been amended to incorporate the limitations of claim 13. Applicants submit that the amendments of claim 9 remove the rejection.

Claims 1-7 and 17-21 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Aoki et al. Claims 1-7 and 17-21 have been canceled, rendering the rejection moot.

Claims 1-5, 7-12, and 15-19 and 21, as product claims, were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Van Belle et al. Claims 1-5, 7, 10 and 17-19 and 21 have been canceled, rendering the rejection moot as applied to these claims. The Office action states that Van Belle et al. teaches a product including a DNA encoding HGF, and that claims 11-12 and 15-16 were rejected over Van Belle "as a product" (see the Office action at page 14). Claim 9 has been amended to clarify that a process is claimed, and to incorporate the limitations of claim 13. Applicants submit that the amendments of claim 9 remove the rejection as applied to claim 9 and claims 11-12 and 15-19, (which depend from claim 9).

Claims 1-5, 7 and 17-19 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Miller et al. Claims 1-5, 7 and 17-19 have been canceled, rendering the rejection moot.

### **Rejections Under 35 U.S.C. § 103**

Claims 1-8 were provisionally rejected under 35 U.S.C. § 103 as allegedly being obvious over co-pending U.S. Application No. 09/857,719. Claims 1-8 have been canceled, rendering the rejection moot.

Claims 1-8 were provisionally rejected under 35 U.S.C. § 103 as allegedly being obvious over co-pending U.S. Application No. 09/029,497. Claims 1-8 have been canceled, rendering the rejection moot.

### **Prior Art and Notice of Reference Cited**

Applicants note that claims 13-14 were free of the cited prior art. Claim 9 has been amended to incorporate the limitations of claim 13; claim 13 has been canceled.

A copy of U.S. Patent No. 5,980,887 (Isner et al.) was attached to the Office action. However, this U.S. Patent was not listed on the form PTO-892 that accompanied the Office action. As this reference was supplied by the Examiner, Applicants requested, in the telephone conference of February 20, 2003, that this U.S. Patent be made of record, and be listed on a form PTO-892 when a further Office action or Notice of Allowance is issued.

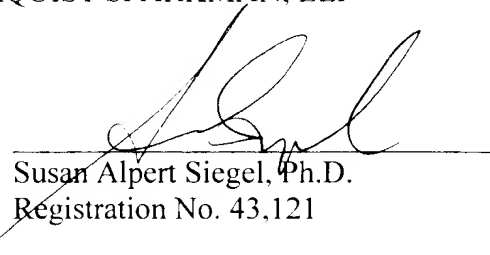
### Conclusion

Applicants submit that claims 9, 11, and 14-16 are in condition for allowance, which action is requested. If any minor matters remain to be addressed before a Notice of Allowance is issued, the Examiner is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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**Marked-up Version of Amended Claims and specification  
Pursuant to 37 C.F.R. §§ 1.121(b)-(c)**

**In the specification:**

**Priority Claim**

This application claims priority under 35 U.S.C. § 371 to PCT Application No. PCT/JP00/07502, filed October 26, 2000, which claims priority to Japanese Patent Application No. 11/309984, filed October 29, 1999[, each of which is incorporated by reference in its entirety herein].

**In the claims:**

*Please cancel claim 1-8.*

9. (Amended) A method for the treatment of diabetic ischemic disease in a subject, comprising  
administering a therapeutically effective amount of a nucleic acid encoding hepatocyte growth factor to the muscle of an ischemic site, thereby treating the diabetic ischemic disease.

*Please cancel claim 10.*

11. (Amended), the method according to claim 9, wherein the diabetic ischemic disease is selected from the group consisting of diabetic lower limb ischemic disease, diabetic ischemic neuropathy, and diabetic ischemic myocardial infarction, thereby treating the ischemic disease.

12. (Reiterated) The method according to claim 11, wherein the diabetic ischemic disease is diabetic lower limb ischemic disease.

*Please cancel claim 13.*

14. (Amended) The method according to claim 9, wherein the nucleic acid encoding the hepatocyte growth factor [gene] is in the form of a Sendai virus (HVJ)-liposome.

15. (Amended) The method according to claim 9, wherein the nucleic acid encoding the hepatocyte growth factor [HGF] is administered repeatedly.

16. (Amended) The method according to claim 9, wherein at least 50  $\mu$ g of the nucleic acid encoding the hepatocyte growth factor [HGF] is administered to the subject.

*Please cancel claims 17-21.*